*1996 U.S. Dist. LEXIS 22739, **

ANTHONY **LOPEZ** and VELMA **LOPEZ,** Plaintiffs, v. **WYETH-AYERST LABORATORIES,** and DOES 1-20, inclusive, Defendants.

No. C 94-4054 CW

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

1996 U.S. Dist. LEXIS 22739

December 13, 1996, Decided
December 13, 1996, Filed

SUBSEQUENT HISTORY: Affirmed, Lopez v. Wyeth-Ayerst Lab., 139 F.3d 905, 1998 U.S. App. LEXIS 11429 (9th Cir. Cal. 1998)

DISPOSITION: [*1] Defendant's motion for summary judgment GRANTED. Action dismissed.

CORE TERMS: flu vaccine, causation, expert testimony, vaccine, scientific, moving party, animal, non-moving, prong, epidemiological, admissible, absence of evidence, summary judgment, non-swine, anecdotal, issue of causation, general population, tort law, scientifically, admissibility, neuritis, scientific evidence, warning, substantive law, material fact, peer review, pre-existing, evidentiary, reliability, regulations

COUNSEL: For ANTHONY LOPEZ, VELMA LOPEZ, Plaintiffs: Brian P. Evans, Brian P. Evans Law Offices, Walnut Creek, CA.

For WYETH-AYERST LABORATORIES, INC., defendant: Stuart M. Gordon, Gordon & Rees, San Francisco, CA.

For WYETH-AYERST LABORATORIES, INC., defendant: Hedy M. Powell, Wyeth-Ayerst Laboratories, Philadelphia, Pa.

For WYETH-AYERST LABORATORIES, INC., defendant: Charles L. Casteel, Davis Graham & Stubbs, Denver, CO.

JUDGES: CLAUDIA WILKEN, UNITED STATES DISTRICT JUDGE.

OPINIONBY: CLAUDIA WILKEN

OPINION: ORDER GRANTING MOTION FOR SUMMARY JUDGMENT

Defendant Wyeth-Ayerst Laboratories ("Wyeth") moves for summary judgment with respect to Plaintiffs' product liability action on the grounds that there is no admissible, scientific evidence that Anthony Lopez's injuries were caused by Wyeth's product. Plaintiffs Anthony and Velma Lopez oppose this motion. The matter was heard on November 15, 1996. Having considered all of the papers filed by the parties and oral argument on the motion, the Court GRANTS the motion.

BACKGROUND

In this biological product liability action, Plaintiffs contend that the 1993-94 Formula Influe Virus Vaccine manufactured and distributed by Wyeth ("1993-94 Wyeth IVV"), a non-swin vaccine, caused Mr. Lopez to develop Guillain-Barre Syndrome ("GBS"). GBS is a neurolog

EXHIBIT
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condition that causes paralysis. While most GBS patients experience complete recovery, approximately 10 to 12% have some kind of permanent impairment.

On October 30, 1993, Mr. Lopez was administered the 1993-94 Wyeth IVV vaccine. He received no warning of any risks associated with the 1993-94 Wyeth IVV vaccine. He began to feel a tingling sensation in his hands and feet on November 3, 1993. On November 6th, 1993 he reported symptoms of weakness, numbness and tingling sensations to a doctor, and on November 7th, 1993, he was admitted to the emergency room with a diagnosis of GBS. GBS left him permanently paralyzed below his knees.

Plaintiffs proffer the expert testimony of Drs. Peter Lichtenfeld and William Patrick Joseph to show a causal link between the flu vaccine and Mr. Lopez's GBS. Dr. Joseph stated that he had not performed any studies regarding the association between a flu vaccine and GBS.

STANDARD OF REVIEW

Summary judgment is properly granted when no genuine and disputed issues of material **[*3]** fact remain, and when, viewing the evidence most favorably to the non-moving party, the movant is clearly entitled to prevail as a matter of law. Fed. R. Civ. P. 56; Celotex Corp. v. Catrett, 477 U.S. 317, 322-23, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986); Eisenberg v. Insurance Co. of North America, 815 F.2d 1285, 1288-89 (9th Cir. 1987).

The moving party bears the burden of showing that there is no material factual dispute. Therefore, the Court must regard as true the opposing party's evidence, if supported by affidavits or other evidentiary material. Celotex, 477 U.S. at 324; Eisenberg, 815 F.2d at 1289. The Court must draw all reasonable inferences in favor of the party against whom summary judgment is sought. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986); Intel Corp. v. Hartford Accident and Indem. Co., 952 F.2d 1551, 1558 (9th Cir. 1991).

Material facts which would preclude entry of summary judgment are those which, under applicable substantive law, may affect the outcome of the case. The substantive law will identify **[*4]** which facts are material. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986).

Where the moving party does not bear the burden of proof on an issue at trial, the moving party may discharge its burden of showing that no genuine issue of material fact remains by demonstrating that "there is an absence of evidence to support the non-moving party's case." Celotex, 477 U.S. at 325. The moving party is not required to produce evidence showing the absence of a material fact on such issues, nor must the moving party support its motion with evidence negating the non-moving party's claim. Id.; Lujan v. National Wildlife Federation, 497 U.S. 871, 885, 111 L. Ed. 2d 695, 110 S. Ct. 3177 (1990); see also Bhan v. NME Hospitals, Inc., 929 F.2d 1404, 1409 (9th Cir. 1991), cert. denied, 502 U.S. 994, 116 L. Ed. 2d 639, 112 S. Ct. 617 (1991). If the moving party shows an absence of evidence to support the non-moving party's case, the burden then shifts to the opposing party to produce "specific evidence, through affidavits or admissible discovery material, to show that the dispute **[*5]** exists." Bhan, 929 F.2d at 1409. A complete failure of proof concerning an essential element of the non-moving party's case necessarily renders all other facts immaterial. Celotex, 477 U.S. at 323.

DISCUSSION

In order to establish causation for their claims, Plaintiffs must present admissible evidence that (1) the 1993-94 Wyeth IVV vaccine can cause GBS (general causation), and (2) that it did in fact cause Mr. Lopez's GBS (specific causation). Casey v. Ohio Medical Products, 877 F. Supp. 1380, 1382 (N.D. Cal. 1995); see also Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1320 (9th Cir. 1995), cert. denied 516 U.S. 869, 116 S. Ct. 189, 133 L. Ed. 2d 126 (1995) ("Daubert II") (under California tort law, plaintiffs must prove that their injuries were the result of the accused cause and not some independent factor).

Wyeth contends that there is an absence of evidence to support to support Plaintiffs' case on the issue of causation. According to Wyeth, Plaintiffs have no scientifically valid evidence to establish that the 1993-94 Wyeth IVV vaccine can cause GBS, in general, **[*6]** or that it did cause Mr. Lopez's GBS. Specifically, Wyeth alleges that Plaintiffs' experts' opinions are not admissible under Federal Rule of Evidence 702 because they neither meet the "scientific knowledge" prong nor the helpfulness prong of the test for admissibility of expert testimony as set out in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 591-92, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993) ("Daubert I").

Plaintiffs argue that because their expert opinions meet the Daubert I requirements, they are admissible, and that they establish the causation element of their prima facie case.

A. Admissibility of Expert Scientific Testimony

In determining the admissibility of expert scientific testimony under Federal Rule of Evidence 702, the Court must engage in a two part analysis: (1) to determine reliability, the Court must decide whether the expert testimony reflects or pertains to scientific knowledge; and (2) to determine relevance, the Court decide whether the expert testimony logically advances a material aspect of the proposing party's case. Daubert II, 43 F.3d at 1315 (citing Daubert I, 509 U.S. at 589-96); **[*7]** see also Lust v. Merrell Dow Pharmaceuticals, Inc., 89 F.3d 594, 597 (9th Cir. 1996).

1. Basis in scientific knowledge

To determine whether the expert testimony is based on scientific knowledge, the Court may consider the following factors: "whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known or potential rate of error is acceptable." Daubert 43 F.3d at 1316 (citing Daubert I, 509 U.S. at 592-94). These factors are merely illustrative, not exhaustive nor definitive. Daubert 43 F.3d at 1316-17. The focus of this inquiry "is not on the correctness of the expert's conclusions, but on the soundness of his methodology." Id. at 1318.

Another factor is whether the opinions were based on pre-existing independent research, or were expressly formed for the purposes of testifying. Id. at 1317. In this case, Plaintiffs' experts' opinions are not based on their own, pre-existing, independent research. Where the expert testimony is not based on independent research, the party offering it "must **[*8]** come forward with other objective, verifiable evidence that the testimony is based on 'scientifically valid principles'", such as peer-reviewed publications. Id. at 1317-18. Alternatively, the experts must explain precisely how they went about reaching their conclusions and point to some objective source to show that they have followed the scientific method. Id. at 1319.

In this case, Plaintiffs' expert Dr. Lichtenfeld relies on the following as the basis for his opinion: the fact that an influenza vaccine is one of the recognized antecedent events to the onset of GBS; the fact that Mr. Lopez's medical records showed no other precursor event; a number of anecdotal reports in the medical literature of neurologic reaction to the flu vaccine; two animal studies; and case reports. Plaintiffs' other expert, Dr. Joseph, relies on similar information.

Plaintiffs also say that their experts are relying on epidemiological studies. However, they do not cite any studies, other than swine-flu vaccine studies, to support their opinions. Rather, they seem to argue that epidemiological studies are not very helpful in addressing the causes of GBS because of problems with reporting. They **[*9]** cite no authority to support this proposition.

Finally, Plaintiffs say that their experts are relying on Wyeth's product literature, which lists GBS under "adverse reactions," n1 testimony from a Wyeth employee that there is a temporal association between a flu vaccine and GBS, and a 1977 "Dear Doctor" letter than cautioned about the possible association between a flu vaccine and GBS. The Court understands that this evidence tends to show that there is a wide recognition of a possible relationship between a flu vaccine and GBS.

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n1 Plaintiffs argue that this adverse reaction warning has strong evidentiary significance because, pursuant to FDA regulations, such warnings are required as soon as there is significant medical evidence of a possible health hazard. 21 C.F.R. § 201.57(e). However, the FDA regulations also state that "a causal relationship need not have been proved" before such a label is required.

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

For the reasons set forth below, the Court is not convinced that this evidence **[*10]** is sufficient to form a scientifically valid basis for the doctors' opinions under the Daubert I standard.

In essence, Plaintiffs' experts' opinions are based on the fact that the medical community recognizes that there is a possible relationship between a flu vaccine and GBS, that Mr. Lopez had a flu vaccine a short time prior to the onset of GBS, and that Mr. Lopez's medical history does not show any other precursor events. The experts offer no theory to explain how, from this information, they were able to eliminate all other potential causes of GBS.

This is particularly troubling in light of Dr. Joseph's statement that 30 to 40% of the GBS cases have idiopathic or unknown causes, and Wyeth's expert's uncontroverted testimony that there has been no epidemiological study showing increased incidence of GBS in persons receiving a non-swine flu vaccine, such as the 93-94 Wyeth IVV, as compared with persons in the general population. In fact, the epidemiological studies that are available, including one large study using data from U.S. military personnel, have shown that the occurrence of GBS among non-swine flu virus vacinees did not exceed the expected background rates in the **[*11]** general population. Epidemiological evidence is one of the most valuable pieces of scientific evidence of causation. Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 311 (5th Cir. 1989), modified 884 F.2d 166 (5th Cir. 1989), cert. denied 494 U.S. 1046 (1990); Casey v. Ohio Medical Products, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (considering lack of epidemiology study an important factor in determining reliability).

In Daubert II, the Ninth Circuit found the expert testimony based on similar grounds unreliable because the expert failed to offer a theory to explain how he was able to eliminate all other potential causes of the alleged injury. Daubert II, 43 F.3d at 1319.

Additionally, the Court finds other aspects of the experts' opinions troubling. With respect to the anecdotal or case reports, Dr. Lichtenfeld states that there are reports concerning patients who have received a flu vaccine, and who have then developed GBS. However, he does not state whether these anecdotal reports isolate and exclude other potential causes of GBS. Generally, courts have excluded expert causation **[*12]** testimony that is based upon such anecdotal or case reports. See, e.g., Casey v. Ohio Medical Products, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) ("Such case reports are not reliable scientific evidence of causation, because they simply describe reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation.")

With respect to the animal studies, Dr. Lichtenfeld states that the studies show that a flu vaccine was capable of inducing or contributing to allergic neuritis, which is an animal equivalent of GBS. While at least one of the studies has been subject to peer review, Dr. Lichtenfeld does not explain how these studies show that a flu vaccine is capable of causing GBS in humans, or the basis for his conclusion that the studies demonstrate causation in humans. An expert's mere citation to animal studies, without more, is not enough to show that the expert's opinion is based upon scientific knowledge. See Daubert II, 43 F.3d at 1319.

For example, Plaintiffs rely upon **[*13]** a copy of a confidential draft of an animal study entitled "Experimental Antigen-Induced Neuritis [EAIN] - a Possible Model for Guillian-Barre Syndrome," in

which the author writes, "Wyeth might find the EAIN model of future use to predict which strains of influenza might give vaccine complications such as GBS. It might also be used to determine which components of the vaccine cause the disease and to eliminate them or modify them."

However, Wyeth's expert explains that this model is distinguishable because it requires an adjuvant, and because animal studies with the vaccine and no adjuvant have not produced experimental neuritis. Plaintiffs do not address these issues.

2. Relevancy of Proffered Expert Testimony

Even if the proffered expert testimony were found to be sufficiently reliable, it must still satisfy the second prong of Daubert I. The second prong requires "a valid scientific connection to the pertinent inquiry as a precondition to admissibility." Daubert I, 509 U.S. at 592. In this case the pertinent inquiry concerns the issue of causation.

In assessing whether the proffered expert testimony will assist the trier of fact in resolving this **[*14]** issue, the Court must look to the governing substantive standard, which in this case is supplied by California tort law. Daubert II, 43 F.3d at 1320. Under California tort law, Plaintiffs must prove that their injuries were, more likely than not, the result of the accused cause and not some independent factor. Id.

In this case, Plaintiffs have not made the requisite showing of relevance. Even if they have established that some flu vaccine is capable of causing GBS, they have not established that the 93-94 Wyeth IVV, the flu vaccine at issue in this case, is capable of causing GBS. Nor have they established that there is any significant, increased incidence rate of GBS in persons receiving a non-swine flu vaccine, such as the Wyeth IVV, above the normal population. In short, they have not met the relevancy standard required by Daubert I.

Because the proffered testimony does not satisfy either prong of the Daubert I test, it is not admissible. Without this testimony, there is an absence of evidence to support Plaintiffs' case on the issue of causation, and Wyeth must prevail.

CONCLUSION

For the foregoing reasons, Defendant's motion is GRANTED.

IT IS **[*15]** SO ORDERED.

Dated: DEC 13 1996

CLAUDIA WILKEN

UNITED STATES DISTRICT JUDGE

JUDGMENT - ENTERED IN CIVIL DOCKET DEC 17 1996

This action came on for hearing before the Court, the Honorable Claudia Wilken, United States District Judge, presiding, and the issues having been duly heard and the Court having duly rendered its decision as set forth in its Order Granting Motion for Summary Judgment filed December 13, 1996,

IT IS HEREBY ORDERED AND ADJUDGED:

That Plaintiffs Anthony Lopez and Velma Lopez take nothing, that the action be dismissed on the merits, and that Defendant Wyeth-Ayerst Laboratories recover of Plaintiffs its costs of action.

Dated: DEC 13 1996

CLAUDIA WILKEN

UNITED STATES DISTRICT JUDGE

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*2000 U.S. App. LEXIS 8601, **

ROBERT S. **WASHBURN,** Plaintiff, LILLIAN E. AWAD, Plaintiff-Appellant, -v- **MERCK & CO.**, INC., Defendant-Appellee.

No. 99-9121

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

2000 U.S. App. LEXIS 8601

May 1, 2000, Decided

NOTICE: [*1] RULES OF THE SECOND CIRCUIT COURT OF APPEALS MAY LIMIT CITATION TO UNPUBLISHED OPINIONS. PLEASE REFER TO THE RULES OF THE UNITED STATES COURT OF APPEALS FOR THIS CIRCUIT.

PRIOR HISTORY: Appeal from the United States District Court for the Southern District of New York (Stanton, J.).

DISPOSITION: AFFIRMED.

CASE SUMMARY

PROCEDURAL POSTURE: Plaintiff appealed the judgment of the United States District Court for the Southern District of New York, which granted summary judgment in favor of defendant in plaintiff's action claiming that as a result of receiving a certain rubella vaccine, she developed arthralgia, chronic arthropathy and chronic pain syndrome.

OVERVIEW: Plaintiff commenced an action against defendant, claiming that as a result of receiving the Meruvax II rubella vaccine, she developed arthralgia, chronic arthropathy and chronic pain syndrome. The district court granted summary judgment in favor of defendant holding that, pursuant to the Daubert standard, plaintiff's expert testimony was not admissible under Fed. R. Evid. 702 and 703, and therefore plaintiff could not have proven causation. On appeal, the court concluded that the district court did not abuse its discretion in determining that plaintiff's expert testimony was unreliable because it was based on little more than temporal correlation between plaintiff's vaccination and the onset of symptoms. Plaintiff's expert testimony did not appear to have been grounded in scientifically valid methodology or reasoning and thus was inadmissible under the Daubert standard. Plaintiff's ill-supported contention that defendant's epidemiological studies were flawed was rejected.

OUTCOME: Judgment affirmed; the district court properly applied the Daubert standard and did not abuse its discretion in excluding the testimony of plaintiff's experts, and absent admissible evidence of causation, defendant was entitled to summary judgment.

CORE TERMS: chronic, arthritis, symptoms, rubella vaccine, vaccination, expert testimony, rubella, pain, methodology, causation, causal relationship, vaccine, Vaccine Act, arthralgia, excluding, summary judgment, epidemiological, fibromyalgia, arthropathy, onset, scientifically, inadmissible, admissible, admissible evidence, temporal proximity, anecdotal, grounded, temporal, syndr... swelling

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Civil Procedure > Summary Judgment
Civil Procedure > Appeals > Standards of Review > De Novo Review
HN1 The appellate court reviews de novo the district court's grant of summary judgment. More Like This Headnote

Civil Procedure > Appeals > Standards of Review > Abuse of Discretion
HN2 The district court's exclusion of expert testimony pursuant to the Daubert standard will be affirmed unless it constituted an abuse of discretion. More Like This Headnote

Evidence > Witnesses > Expert Testimony
Criminal Law & Procedure > Evidence > Scientific Evidence > Daubert Standard
HN3 Under the Daubert standard, expert testimony is admissible under Fed. R. Evid. 702 only if the trial court determines that it is both relevant and reliable. The trial court is charged with making a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue. In analyzing scientific validity, the trial court considers, among other things, (1) whether the expert's theory is capable of being tested; (2) whether the theory has been scrutinized by others in the field by means of peer review or publication; (3) the known or potential error rate associated with the underlying technique; (4) whether standards and controls have been used in testing; and (5) whether the technique and theory (not the conclusions) at issue are generally accepted in the particular scientific community. More Like This Headnote

COUNSEL: Appearing for Appellant: Anthony P. Gentile, Godosky & Gentile, P.C., New York, NY.

Appearing for Appellee: Richard L. Josephson, Baker Botts L.L.P., Houston, TX.

JUDGES: Present: ROSEMARY S. POOLER, SONIA SOTOMAYOR, * Circuit Judges.

* Judge Van Graafeiland, who was originally assigned as a member of the panel designated to hear this appeal, became ill shortly before the scheduled oral argument and was unable to participate in its argument or disposition. The remaining two members of the panel, who agree on the disposition, issue this order pursuant to 2d Cir. R. § 0.14(a), (b). See Murray v. National Broadcasting Co., Inc., 35 F.3d 45, 47-48 (2d Cir. 1994).

OPINION: SUMMARY ORDER

ON CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the order of said District Court be and it hereby is **AFFIRMED.**

Lillian E. Awad appeals from an order of the **[*2]** United States District Court for the Southern District of New York (Stanton, J.) granting summary judgment in favor of defendant Merck & Co., Inc. ("Merck"). In 1989, Awad was a graduate student and worked at Albert Einstein Medical Center as a lab technician. Pursuant to New York law, Awad's employer routinely administered rubella (German measles) vaccinations to its female health care workers of child-bearing age. On July 6, 1989, Awad received Meruvax II, which is Merck's brand of Wistar Institute RA 27/3, a live virus vaccine against rubella. Subsequent to her vaccination, Awad developed an acute illness, which included swelling of joints, rash and flu-like symptoms. Over the course of the next year, Awad continued to experience joint and muscle pain and her treating physicians diagnosed her with chronic arthropathy, chronic pain syndrome, and fibromyalgia.

Awad commenced this action against Merck in October 1995, claiming that as a result of receiving the Meruvax II rubella vaccine, she developed arthralgia, chronic arthropathy and chronic pain syndrome. Merck moved for summary judgment, claiming that Awad's evidence of causation was

inadmissible under the Federal Rules of **[*3]** Evidence and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993). In addition, Merck claimed that plaintiff's claims were barred under the National Childhood Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-1, et seq. ("Vaccine Act"). The district court granted summary judgment in favor of Merck holding that, pursuant to Daubert, plaintiff's expert testimony was not admissible under Fed. R. Evid. 702 and 703, and therefore plaintiff could not prove causation. The district court did not address the Vaccine Act claim. On appeal, Awad argues that the district court abused its discretion in excluding her causation testimony and exceeded its gatekeeping role by determining an issue which should have been decided at trial. For the reasons below, we reject appellant's arguments and affirm the judgement of the district court.

HN1 We review de novo the district court's grant of summary judgment. See Wilkinson v. Russell, 182 F.3d 89, 96 (2d Cir. 1999). HN2 The district court's exclusion of expert testimony pursuant to Daubert v. Merrell Dow will be affirmed unless it constituted **[*4]** an abuse of discretion. See General Elec. Co. v. Joiner, 522 U.S. 136, 142, 139 L. Ed. 2d 508, 118 S. Ct. 512 (1997). HN3 Under Daubert, expert testimony is admissible under Rules 702 of the Federal Rules of Evidence only if the trial court determines that it is both relevant and reliable. See Daubert, 509 U.S. at 589-90. The trial court is charged with making a "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Id. at 592-93. In analyzing scientific validity, the trial court considers, among other things, 1) whether the expert's theory is capable of being tested; 2) whether the theory has been scrutinized by others in the field by means of peer review or publication; 3) the known or potential error rate associated with the underlying technique; 4) whether standards and controls have been used in testing; and 5) whether the technique and theory (not the conclusions) at issue are generally accepted in the particular scientific community. Id. at 593-94.

In this **[*5]** case, the district court rejected the testimony of Doctors Lans, Dorsch and Wetherbee on the issue of causation and concluded that their opinions were based largely on the temporal proximity of the vaccination to the onset of Awad's symptoms and were not grounded in the methods of science. Appellant contends that while there is genuine disagreement in the medical research community as to whether there is a link between the rubella vaccine and the development of chronic joint pain and the symptoms associated with her illness, she nevertheless offered admissible evidence as to causation. For example, appellant argues that Judge Stanton improperly dismissed a 1979 study by Aubrey Tingle in which several women showed evidence of acute and chronic arthritis and arthralgia conditions merely because it studied a small population and only two of the subjects actually received RA 27/3, as opposed to its predecessor vaccine. In response, Merck acknowledges that during the 1980s, several researchers hypothesized that there could be a link between rubella vaccines and chronic arthritis. As Merck points out, Awad does not complain of arthritis, which is characterized by objectively observable **[*6]** swelling of the joints, but rather arthropathy, arthralgia and chronic fibromyalgia, which are characterized by more subjective symptoms. Furthermore, the evidence linking the vaccine with arthritis is derived mainly from anecdotal reports and small population studies with few controls. Merck also argues that while an Institute of Medicine Report in 1991 suggested a connection between rubella vaccine and chronic arthritis, and suggested ways in which such a study could be conducted, it noted, significantly, that such a "relation between rubella vaccine and chronic arthritis remains unproved." Since that report, three large, controlled epidemiological studies found no evidence of a causal relationship between immunization with RA27/3 rubella vaccine and persistent joint symptoms or other chronic joint disease conditions. In addition, one study that specifically examined the association between Meruvax II and fibromyalgia found no causal relationship between the two.

We conclude that the district court did not abuse its discretion in determining that plaintiff's expert testimony was unreliable because it was based on little more than temporal correlation between Awad's vaccination and **[*7]** the onset of symptoms. See Cavallo v. Star Enterprise, 892 F. Supp. 756 (E.D. Va. 1995), aff'd in relevant part, 100 F.3d 1150 (4th Cir. 1996); Conde v. Velsicol Chem. Corp., 804 F. Supp. 972, 1023 (S.D. Ohio 1992), aff'd 24 F.3d 809 (6th Cir. 1994). Dr. Dorsch provided only conclusory statements that Awad had "polyarthralgias, most likely resulting from

Rubella vaccine." Taking into account an array of factors consistent with Daubert, Judge Stanton properly rejected Dorsch's conclusion that Awad's joint condition was related to the rubella vaccine because it was supported by nothing more than temporal proximity. Similarly, it was well within the discretion of the district court to exclude the unsubstantiated opinion of Dr. Lans that Awad's condition was the result of vaccination. Nor are we persuaded that the district court erred in excluding the testimony of Dr. Wetherbee. Based on his review of Awad's medical records, studies linking the rubella virus with chronic arthritis, and the temporal relationship between vaccination and onset of symptoms, Wetherbee opined that appellant's chronic joint pain resulted from Meruvax **[*8]** II. The district court emphasized that Wetherbee's opinion did not emanate from his own research in the field, but rather was developed for purposes of litigation. Judge Stanton reviewed the articles on which Wetherbee based his opinion and evaluated the validity of the methodology under Daubert. Judge Stanton reviewed the studies and articles that Wetherbee used to conclude that there is a causal relationship between RA 27/3 and chronic joint conditions and found that none was a large-scale epidemiological study and most were either anecdotal, or did not involve RA 27/3. We conclude that it was well within Judge Stanton's discretion to exclude Wetherbee's testimony. Plaintiff's expert testimony does not appear to be grounded in scientifically valid methodology or reasoning and thus is inadmissible under Daubert. Finally, we reject appellant's ill-supported contention that Merck's epidemiological studies (which show no causal relationship between RA 27/3 and chronic joint problems) are flawed.

We conclude that the district court properly applied the Daubert standard and did not abuse its discretion in excluding the testimony of plaintiff's experts. Absent admissible evidence **[*9]** of causation, Merck was entitled to summary judgment. There is no need for us to consider the parties' arguments related to the Vaccine Act. Accordingly, we affirm the judgment of the district court.

We have examined all of the appellant's contentions and find them to be without merit.

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*2004 U.S. Dist. LEXIS 9859, **

JOSEPH W. **FABRIZI,** Plaintiff, v. REXALL SUNDOWN, INC., d/b/a, SUNDOWN VITAMINS, Defendant.

Civil Action No. 01-289

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

2004 U.S. Dist. LEXIS 9859

June 2, 2004, Decided

DISPOSITION: [*1] Recommended that Defendant's Motions to Exclude the Testimony of Plaintiff's Expert Witnesses be granted and summary judgment should be entered in favor of Defendant..

CASE SUMMARY

PROCEDURAL POSTURE: Plaintiff individual filed suit against defendant, a manufacturer and distributor of an herbal supplement, alleging claims of negligence, strict liability, and breach of warranty. The manufacturer filed a motion to exclude the testimony of the individual's expert witnesses. The matter was referred to a magistrate for report and recommendation.

OVERVIEW: The individual alleged that his ingestion of the supplement caused him to develop cataracts in both eyes, resulting in various physical and mental injuries. After filing suit, the individual's counsel employed the services of a board-certified medical internist. The internist purported to opine, with a reasonable degree of medical certainty, that the individual's cataracts were caused or accelerated by his ingestion of the supplement. The internist had neither examined nor interviewed the individual. The internist claimed heavy reliance on "clinical trial data," opinions, and his consultation with the individual's second expert, an organic chemist who specialized in the study of "ocular toxicity" and "phototoxicity." The magistrate found that the opinions of the chemist were inadmissible. The magistrate reasoned that her research was insufficient to support a theory of general causation to any reasonable degree of certainty. Next, the magistrate found that the testimony and opinions of the internist were likewise inadmissible. The magistrate reasoned that, as to general causation, the internist in large part piggy-backed on the opinions of the chemist.

OUTCOME: The magistrate recommended that the motions to exclude be granted. The magistrate also recommended that summary judgment should be entered in favor of the manufacturer.

CORE TERMS: causation, hypericin, cataract, animal, expert testimony, ocular, chemical, scientific, lens, reliable, fluorescence, ophthalmologist, reliability, ingestion, summary judgment, fluorometry, differential diagnosis, quotations, vitro, qualification, expertise, vivo, admissibility, formation, exposure, treating, illness, patient, doctor, tissue

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Evidence > Witnesses > Expert Testimony

HN1 Under Pennsylvania law, product liability claim presenting no obvious causal relationship

EXHIBIT C

must be supported by expert testimony regarding causation. More Like This Headnote

Evidence > Witnesses > Expert Testimony

HN2 See Fed. R. Evid. 702.

Evidence > Witnesses > Expert Testimony

HN3 In the United States Court of Appeals for the Third Circuit, Fed. R. Evid. 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit. More Like This Headnote

Evidence > Witnesses > Expert Testimony

HN4 In the United States Court of Appeals for the Third Circuit, in the context of Fed. R. Evid. 702, qualification refers to the requirement that the witness possess specialized expertise. The Third Circuit has interpreted this requirement liberally, holding that a broad range of knowledge, skills, and training may qualify an expert. More Like This Headnote

Evidence > Witnesses > Expert Testimony

HN5 In the United States Court of Appeals for the Third Circuit, in the context of Fed. R. Evid. 702, the testimony must be reliable; it must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation, and the expert must have good grounds for his on her belief. In sum, Daubert holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity. More Like This Headnote

Evidence > Witnesses > Expert Testimony

HN6 In the United States Court of Appeals for the Third Circuit, Fed. R. Evid. 702, requires that the expert testimony must "fit" the issues in the case. In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact. Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility. More Like This Headnote

Torts > Products Liability > Breach of Warranty

Torts > Products Liability > Misrepresentation

Torts > Products Liability > Negligence

Torts > Products Liability > Strict Liability

HN7 In Pennsylvania, proof of causation is a necessary element in a products liability action, regardless of whether the plaintiff's claims sound in negligence, strict product liability, misrepresentation, or breach of warranty. More Like This Headnote

Evidence > Witnesses > Expert Testimony

Torts > Causation > Cause in Fact

Torts > Causation > Proximate Cause

HN8 Pennsylvania law makes clear, that unequivocal medical testimony is necessary to establish the causal connection in cases where there is no obvious relationship between the accident and the injury. This standard corresponds with Pennsylvania's requirement that the plaintiff's injury did, with a reasonable degree of medical certainty, flow from the complained of act. More Like This Headnote

Evidence > Witnesses > Expert Testimony

Torts > Causation > Cause in Fact

Torts > Causation > Proximate Cause

HN9 Pennsylvania's "reasonable degree of medical certainty" standard is both a rule of admissibility and part of the plaintiff's burden of proof. Thus, a defendant is entitled to summary judgment when the plaintiff's expert is unable to testify that the plaintiff's injury

was caused by the defendant's product with a reasonable degree of medical certainty. More Like This Headnote

Torts > Causation > Cause in Fact
Torts > Causation > Proximate Cause
HN10 To meet his causation burden in toxic tort cases, the plaintiff must first establish that the substance in question is capable of causing in humans the injury alleged; this is known as general causation. Then the plaintiff must establish that, in his particular case, the substance did in fact cause the injury he alleges, i.e., specific causation. More Like This Headnote

Evidence > Witnesses > Expert Testimony
HN11 Fed. R. Evid. 702 requires that the expert's testimony must assist the trier of fact. Thus, admissibility depends in part on the proffered connection between the scientific research and particular disputed factual issues in the case. More Like This Headnote

Evidence > Witnesses > Expert Testimony
HN12 In the context of Fed. R. Evid. 702, animal studies may be methodologically acceptable to show that chemical X increases the risk of cancer in animals, but they may not be methodologically acceptable to show that chemical X increases the risk of cancer in humans. Daubert explains that, "fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. Thus, even if an expert's proposed testimony constitutes scientific knowledge, his or her testimony will be excluded if it is not scientific knowledge for purposes of the case. Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility. More Like This Headnote

Evidence > Witnesses > Expert Testimony
HN13 In the context of Fed. R. Evid. 702, in order for animal studies to be admissible to prove causation in humans, there must be good grounds to extrapolate from animals to humans, just as the methodology of the studies must constitute good grounds to reach conclusions about the animals themselves. Thus, the requirement of reliability, or "good grounds," extends to each step in an expert's analysis all the way through the step that connects the work of the expert to the particular case. More Like This Headnote

Evidence > Witnesses > Expert Testimony
HN14 In the context of Fed. R. Evid. 702, courts addressing animal studies commonly have identified the "extrapolation" inquiry as an important, if not threshold, determination for the purposes of both "fit" and "reliability." More Like This Headnote

Evidence > Witnesses > Expert Testimony
HN15 Fed. R. Evid. 702 does not permit expert testimony based on subjective belief or unsupported speculation. More Like This Headnote

Torts > Causation > Cause in Fact
Torts > Causation > Proximate Cause
HN16 If a plaintiff has not demonstrated sufficiently reliable evidence of general causation, his claims fail and there is no need to consider specific causation. More Like This Headnote

Evidence > Witnesses > Expert Testimony
HN17 A person, although qualified as an expert in one area of expertise, may be precluded from offering opinions beyond that area of expertise. More Like This Headnote

Evidence > Witnesses > Expert Testimony
Torts > Causation > Cause in Fact

Torts > Causation > Proximate Cause

HN18 Pennsylvania law requires unequivocal medical testimony of causation, offered to a reasonable degree of medical certainty. More Like This Headnote

Evidence > Witnesses > Expert Testimony

HN19 Expert testimony that simply parrots the opinion of another does not assist the trier of fact, and thus, is inadmissible under Fed. R. Evid. 702. More Like This Headnote

Evidence > Witnesses > Expert Testimony

HN20 Reliance on anecdotal case reports to support an expert's causation opinion is contrary to both good scientific practice and the Daubert case law. More Like This Headnote

Evidence > Witnesses > Expert Testimony

HN21 An expert's level of expertise may affect the reliability of his opinion. More Like This Headnote

Evidence > Witnesses > Expert Testimony

HN22 When a physician who has never examined the plaintiff renders opinions solely for the purpose of advancing a lawsuit, said opinions will be met with at least some degree of skepticism under the law. More Like This Headnote

Evidence > Witnesses > Expert Testimony

HN23 The Daubert inquiry evaluates whether an expert is a hired gun or a person whose opinion in the courtroom will withstand the same scrutiny that it would among his professional peers. More Like This Headnote

Evidence > Witnesses > Expert Testimony

HN24 The performance of physical examinations, taking of medical histories, and employment of reliable laboratory tests all provide significant evidence of a reliable differential diagnosis, and that their absence makes it much less likely that a differential diagnosis is reliable. These techniques are generally accepted as a standard part of differential diagnosis, and such techniques significantly reduce the likelihood of erroneous results. Moreover, performance of standard diagnostic techniques provides prima facie evidence that a doctor has considered alternate causes and has attempted to test his or her initial hypothesis as to cause. More Like This Headnote

Civil Procedure > Summary Judgment > Summary Judgment Standard

Evidence > Witnesses > Expert Testimony

Torts > Causation > Cause in Fact

Torts > Causation > Proximate Cause

HN25 Where a plaintiff fails to present admissible expert testimony regarding causation, courts routinely have granted summary judgment in favor of the defendant. More Like This Headnote

COUNSEL: For JOSEPH W. FABRIZI, plaintiff: Robert B. Woomer, Woomer & Friday, Pittsburgh, PA.

For REXALL SUNDOWN, INC., a corporation dba SUNDOWN VITAMINS, defendant: Kenneth S. Mroz, Swartz Campbell, Pittsburgh, PA.

JUDGES: FRANCIS X. CAIAZZA, Chief U.S. Magistrate Judge. Judge Standish.

OPINIONBY: FRANCIS X. CAIAZZA

OPINION: MAGISTRATE JUDGE'S REPORT AND RECOMMENDATION

I. RECOMMENDATION

It is respectfully recommended that the Defendant's Motions to Exclude the Testimony of the Plaintiff's Expert Witnesses (Docs. 53 & 55) be granted. Based on the Plaintiff's failure to proffer admissible expert testimony regarding causation, moreover, summary judgment should be entered in favor of the Defendant.

II. REPORT

BACKGROUND

The Plaintiff Joseph W. Fabrizi ("Mr. Fabrizi" or "the Plaintiff") filed this action against Rexall Sundown, Inc. ("Rexall" or "the Defendant") in state court. *See generally* Compl., attached to Notice of Removal (Doc. 1). Rexall manufactured and distributed an herbal supplement, St. John's Wort, allegedly taken **[*2]** by Mr. Fabrizi. *See generally* Compl. at P3. The Plaintiff claims that his ingestion of the supplement caused him to develop cataracts in both eyes, resulting in various physical and mental injuries. *See generally id.* at PP5-6. The Plaintiff brings claims sounding in negligence, strict liability, and breach of warranty. *See id.,* Counts I-III.

The Defendant removed the case to federal court on the basis of diversity jurisdiction. *See generally* Notice of Removal. As discovery wound down, Defense counsel raised for the first time the Plaintiff's need to introduce expert testimony regarding causation. *Cf. generally* Def.'s Br. in Supp. of 1st Mot. for Summ. J. (Doc. 10) at 1 (HN1 under Pennsylvania law, product liability claim presenting "no obvious causal relationship" must be supported by expert testimony regarding causation) (citations omitted). Since that time, and multiple requests for summary judgment later, the expert issue has taken center stage in this litigation. The Plaintiff's efforts to secure expert testimony, and the nature and content of the opinions obtained, may be summarized as follows.

Before filing suit, Mr. Fabrizi asked his treating ophthalmologist, **[*3]** E. Ronald Salvitti, M.D. ("Dr. Salvitti"), whether his cataracts could be attributed to his ingestion of St. John's Wort. *See* Pl.'s Dep. Tr. (excerpts attached as unnumbered Ex. to Doc. 54) at 62-63. Dr. Salvitti responded that he could not say, "with reasonable [medical] certainty[,] that [Mr. Fabrizi's] condition was related to use of" the supplement. *See* Dep. Tr. of Dr. Salvitti (excerpts attached as unnumbered Ex. to Doc. 54) at 6; *see also* Dr. Salvitti's Ltr. to Pl. dated Aug. 21, 2000 ("as you know, there are other medications, genetic factors and certain types of medical illnesses that contribute to the development of cataracts [,] . . . and probably more commonly, cataracts are seen without explanation in approximately 80% of patients"). n1

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n1 Mr. Fabrizi's cataracts initially were detected by Dr. Richard Stout, an ophthalmologist who in 1996 performed laser surgery on the Plaintiff to correct moderate nearsightedness. *Cf. generally* Expert Report of C. Lamperski, M.D. dated Dec. 14, 2001 (attached as Ex. A to Doc. 59) at 1 (noting "photorefractive keratectomy" ("PRK") performed by Dr. Stout in 1996); *cf. also* website at http://www.eyemdlink.com/EyeProcedure.asp?EyeProcedureID=7 (PRK "is a procedure in which the surface of the cornea is reshaped by an ophthalmologist using an Excimer laser"). Upon discovering the cataracts, Dr. Stout referred the Plaintiff to Dr. Salvitti, who performed surgery to remove the cataracts and treated him thereafter. *See generally* Pl.'s Dep. Tr. at 63; Dep. Tr. of Dr. Salvitti at 5. The Plaintiff never sought Dr. Stout's opinion regarding whether his cataracts may have been caused by St. John's Wort. *See* Pl.'s Dep. Tr. at 63 ("I don't think I ever saw [Dr. Stout] after . . . he referred me to Dr. Salvitti").

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - **[*4]**

After filing suit, Plaintiff's counsel employed the services of Christopher V. Lamperski, M.D. ("Dr. Lamperski"). Dr. Lamperski is a board-certified medical internist who, since July 2001, has acted full time as a medical consultant in legal cases. *See generally* Aff. of Dr. Lamperski (Doc. 43) at P1 & Ex. A thereto; Dep. Tr. of Dr. Lamperski at 54. n2 In a report dated December 14, 2001, Dr. Lamperski purported to opine, "with a reasonable degree of medical certainty, that Mr. Fabrizi's cataracts were caused or accelerated by [his] ingestion of St. John's Wort." *See* Dr. Lamperski's Report at 3.

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n2 The full deposition transcripts of the Plaintiff's two experts, Dr. Lamperski and Joan E. Roberts, Ph.D., have been submitted for the court's consideration. The transcripts have not been docketed, but are contained in the case file.

- - - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

Dr. Lamperski has neither examined nor interviewed the Plaintiff. *See generally* Dep. Tr. of Dr. Lamperski at 16, 20. Nor has he spoken to Mr. Fabrizi's treating ophthalmologist(s) **[*5]** regarding the subject matter of this case. *See id.* at 21. Rather, Dr. Lamperski has formed his opinions based on a review of the treating physicians' records, his discussions with Plaintiff's counsel, and his review of medical literature, "hard copy" and "on-line," regarding "anecdotal reports" of premature cataract development in St. John's Wort users. *See id.* at 58; *see also generally* Dr. Lamperski's Report at 3. More recently, Dr. Lamperski has claimed heavy reliance on the "clinical trial data," opinions, and his consultation with the Plaintiff's second expert, Joan E. Roberts, Ph.D. ("Dr. Roberts").

Dr. Roberts is an organic chemist who specializes in the study of "ocular toxicity" and "phototoxicity." *See generally* Dep. Tr. of Dr. Roberts at 12. Stated more plainly, Dr. Roberts "studies the biological effects of . . . toxic agents in the eye." *See id.* at 11. In a report dated May 28, 2002, she opined, "within a reasonable degree of scientific certainty, that ingestion" of the active ingredient in St. John's Wort, hypericin, "coupled with exposure to sunlight leads to the . . . formation of cataracts in humans." *See* Dr. Roberts' Report (attached as unmarked **[*6]** Ex. to Doc. 56) at 2. She also purports to opine, based on medical data/history of an unknown origin, "that the development of Mr. Fabrizi's cataracts was caused by his ingestion of St. John's Wort." *See id.* at 3. n3

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n3 Dr. Roberts never examined the Plaintiff or his medical records. *See, e.g.*, Dep. Tr. of Dr. Roberts at 9-10, 25-27. Presumably, then, her opinion regarding the cause of Mr. Fabrizi's cataracts, specifically, was based on information and representations provided by Plaintiff's counsel. *Cf. id.* at 26.

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Dr. Roberts' general theory of causation is as follows. When St. John's Wort is ingested by a human being, hypericin enters the bloodstream and finds its way into either the person's "aqueous," *i.e.*, the "fluid that surrounds" and "feeds the lens," or the lens of the eye itself. *See generally* Dep. Tr. of Dr. Roberts at 183, 236. Once present in "those components of the eye," the hypericin absorbs "UV and visible" light introduced through the environment. *See generally id.* 67, **[*7]** 183. A reaction between hypericin and the light occurs, disrupting "the orderly arrangement of . . . protein fibers in the lens[es] and causing [them] to become clouded." *See generally id.* at 17; *cf. also generally id.* at 242. It is through this process that cataracts allegedly are formed. *Cf. generally id.* at 17, 20.

In support of this theory, Dr. Roberts relies on her participation in two research studies. Results of

both studies were published in the year 2000, and Plaintiff's counsel has attached the articles to Mr. Fabrizi's brief in opposition to the *Daubert* Motion (Doc. 58). *See* K.L. Schey, S. Patat, C.F. Chignell, M. Datillo, R.H. Wang & J.E. Roberts, *Photooxidation of Lens [alpha] -Crystallin by Hypericin (Active Ingredient in St. John's Wort),* PHOTOCHEMISTRY & PHOTOBIOLOGY, 72(2): 200-203 (2000); A. Sgarbossa, N. Angelini, D. Gioffre', T. Youssef, F. Lenci & J.E. Roberts, *The Uptake, Location and Fluorescence of Hypericin in Bovine Intact Lens,* 21 CURRENT EYE RESEARCH (No. 2) at 597-601 (2000).

Both of the studies were conducted *in vitro,* which means "in cell or using tissue." *See generally* Dep. Tr. of Dr. Roberts at 83, 173; **[*8]** *cf. also generally* Schering Corp. v. FDA, 51 F.3d 390, 398 n.11 (3d Cir.) ("*in vitro* studies are conducted in an artificial environment such as in laboratory test tubes," and they "do not measure [drug] absorption"; "*in vivo* studies are conducted in [living beings]"), *cert. denied,* 516 U.S. 907, 133 L. Ed. 2d 195 (1995). In the first study alpha-crystalline, "the main protein in the lens that keeps its integrity," was extracted from calf lenses and soaked in a solution containing pure hypericin. *See generally* Dep. Tr. of Dr. Roberts at 153, 154, 160. Irradiation of the solution resulted in "light-induced damage to [the alpha] -crystallin." *See Photooxidation* Article at 203. These findings, coupled with the conclusion hypericin "has . . . [chemical] properties" that "should enable it to cross blood/ocular barriers," led the authors to warn that exposure to the substance, in combination with light, "could lead to the formation of cataracts . . . *in vivo." See id.*

The second study posed that, given the results of the aforementioned research,

> it is essential to determine clinically whether hypericin reaches the human **[*9]** eye and whether it can be phototoxic to ocular tissues. This can be determined in humans, non-invasively, using *in vivo* fluorescence spectroscopy and imaging. To that end, . . . [the researchers] developed a model system to determine the fluorescence characteristics of hypericin when bound to [bovine] ocular tissue.

See Fluorescence Article at 597.

The researchers again soaked calf lens matter, this time intact lenses, in hypericin solution. *See generally id.,* "Methods" section. After a period of "incubation," instruments used to measure fluorescence "confirmed that [the] hypericin [did] bind to the ocular tissues." Based on these results, the scientists concluded:

> The results we obtained in simplified model systems can provide clues to investigate the effects of hypericin on lens properties in physiological conditions.
>
> Hypericin could in fact bind to lens protein[,] thus increasing the retention time of [the substance] in the eye and possibly altering [alpha] -crystallin properties . . . . Therefore, ophthalmologists may use a slit-lamp or scanning fluorometry to monitor the uptake of hypericin in the eyes of patients using St. John's **[*10]** Wort . . . .

See id., "Conclusions" section.

At her deposition, Dr. Roberts clarified the practical implications of the second study, as well as the current state of her research:

> Q. Was ocular fluorometry used to detect hypericin in Mr. Fabrizi's eyes?
>
> A. I have no idea.

Q. Is that a staining technique?

A. No. . . . The eye is clear. You can look through the eye. One of the techniques that I am developing is ocular fluorometry. Fluorometry refers to fluorescence. Fluorescence means the compound lights up. . . . [Like] fluorescent paint, when you paint something and you put a light on it and it lights up[,] that's fluorescence. . . .

> Well, because the eye is clear, you can pass a fluorometer, that is an instrument that measures fluorescence, through the eye to pick up . . . anything that is fluorescent. It is used in ophthalmological examinations all the time, and . . . the whole purpose of . . . the fluorescence [study] was to determine the exact fluorescence that an ophthalmologist might look at in a human eye. . . .

Q. Okay.

A. Something I'm developing. . . .

Q. When you say you're developing this ocular fluorometry, **[*11]** is it perfected . . . yet?

A. The technique of ocular fluorometry is perfected. The use of it to determine hypericin in the eye is undergoing at the moment.

Q. That's something you haven't perfected yet?

A. It's something that I am presently working on . . . .

See Dep. Tr. of Dr. Roberts at 43-45.

Lest there remain any doubt, Dr. Roberts later made clear that the opinions offered here in no way rely upon her continuing efforts to identify the fluorescence of hypericin in the human eye. *See id.* at 208 ("We're [currently] developing it and it's patentable, . . . so I'm not going to discuss it . . . [or] rely on [it in this case]."). Similarly Dr. Roberts has admitted that, at all relevant times, n4 she has neither completed nor relied upon:

> . *in vitro* studies testing whether human alpha-crystalline, when soaked in hypericin and exposed to light, evidenced light-induced damage, *see id.* at 97-99 (studies on human cells were "a work in progress");
>
> . *in vitro* fluorometry studies indicating that hypericin does in fact bind to human lenses, *see id.* at 180;
>
> . *in vivo* studies, in humans or animals, confirming **[*12]** that the ingestion of St. John's Wort leads to the presence of hypericin in the eye, *see id.* at 45-46, 49-50, 51-52, 82-84, 236-37;
>
> . *in vivo* studies, in humans or animals, confirming that the ingestion of St. John's Wort leads to the development or acceleration of cataracts, *see id.* at 141-42, 181; or
>
> . test(s) confirming that hypericin is, or at any time has been, present in Mr. Fabrizi's eyes, *see id.* at 43, 55, 139, 180.

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n4 As referenced below, the parties have stipulated to the court's adjudication of the *Daubert* Motions based on the Plaintiff experts' deposition testimony. *See generally* Stips. filed at Docs. 62 & 64. Even absent such stipulation, the court must draw the line somewhere in terms of the ever-developing courses of study referenced by Dr. Roberts. Moreover, in light of the vast expenditures of time, effort, and resources thus far regarding experts, any request by Plaintiff's counsel to "update" or otherwise supplement the record should be summarily denied. *See generally* discussion *supra; cf. also generally* Mem. Order dated July 30, 2002 (Doc. 44) at 4-5 (noting, as early as July 2002, that Plaintiff "had been somewhat less than timely in prosecuting his case and [his counsel] had engaged in questionable posturing" regarding experts).

- - - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - - **[*13]**

Defense counsel filed the instant Motions, seeking to exclude the opinions and testimony of Drs. Roberts and Lamperski under Federal Rule of Evidence 702 and *Daubert*. *See generally* Def.'s Mots. (Docs. 53 & 55). The parties stipulated that the *Daubert* hearing would be conducted "upon the depositions" and affidavits of the expert witnesses, "without [live] testimony from either expert." *See* Pl.'s Stip. (Doc. 64) at PP5-6; *see also* Def.'s Stip. (Doc. 62) (stating essentially same).

On May 12, 2003, counsel appeared before the undersigned to participate in a *Daubert* hearing, which proceeded in accordance with the parties' stipulation. On March 11, 2004, the parties were invited to engage in a second round of oral argument.

Having carefully considered the parties' positions, as stated during the *Daubert* hearing, at oral argument, and in their briefing, the undersigned now is prepared to offer recommendations regarding the Plaintiff's expert evidence.

ANALYSIS

A. General Standards Applicable Under Rule 702/*Daubert*, Under Pennsylvania Law, and Within the Context of Toxic Tort Litigation.

Federal Rule of Evidence 702 **[*14]** ("Rule 702"), which governs the admissibility of expert testimony, provides:

> HN2 If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

As the Court of Appeals for the Third Circuit recently has explained:

> HN3 Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit. . . .

HN4 Qualification refers to the requirement that the witness possess specialized expertise. We have interpreted this requirement liberally, holding that a broad range of knowledge, skills, and training [may] qualify an expert. . . .

Secondly, HN5 the testimony must be reliable; it must be based on the methods and procedures of science rather **[*15]** than on subjective belief or unsupported speculation[, and] the expert must have good grounds for his on her belief. In sum, *Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity.

Finally, HN6 Rule 702 requires that the expert testimony must [']fit['] the issues in the case. In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

See Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (numerous citations and internal quotations omitted).

Superimposed upon these standards is Pennsylvania's law regarding causation. HN7 "Proof of causation is a necessary element in a products liability action," regardless of whether the plaintiff's claims sound in negligence, strict product liability, misrepresentation, or breach of warranty. *See* Soldo v. Sandoz Pharms. Corp., 244 F. Supp. 2d 434, 524 (W.D. Pa. 2003) (Lee, J.) (citations omitted); *see also* **[*16]** *generally* Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 937 (3d Cir. 1999) (in Pennsylvania, "strict liability, negligence, and breach-of-warranty claims . . . each require[] a proximate connection between the defendant['s] conduct and the plaintiff['s] injury[y]") (citations omitted), *cert. denied,* 528 U.S. 1105, 145 L. Ed. 2d 713 (2000).

HN8 Pennsylvania law makes clear, moreover, that "unequivocal medical testimony is necessary to establish the causal connection in cases where there is no obvious . . . relationship between the accident and the injury." In re Paoli R.R. Yard PCB Litig., 2000 U.S. Dist. LEXIS 12993, 2000 WL 1279922, *2 (E.D. Pa. Sept. 6, 2000) (citations omitted); *accord* Niklaus v. Vivadent, Inc., U.S.A., 767 F. Supp. 94, 96 (M.D. Pa. 1991) (internal quotations and numerous citations omitted), *aff'd,* 986 F.2d 1409 (3d Cir. 1993) (table). This standard corresponds with Pennsylvania's requirement that the plaintiff's injury "did, with a reasonable degree of medical certainty, [flow] from the [complained of] act." Niklaus, 767 F. Supp. at 96 **[*17]** (citation and internal quotations omitted, emphasis in original); *accord* In re Paoli, 2000 U.S. Dist. LEXIS 12993, 2000 WL 1279922 at *2 (citing and quoting Niklaus).

Relatedly, the Third Circuit Court in the seminal case of In re Paoli R.R. Yard PCB Litigation recognized that HN9 Pennsylvania's "reasonable degree of medical certainty" standard is both "a rule of admissibility" and "part of the plaintiff's burden of proof." *See id.,* 35 F.3d 717, 751. Thus, a defendant is entitled to summary judgment "when the plaintiff['s] expert" is unable to "testify that [the] plaintiff's [injury] was caused by [the defendant's product] with a reasonable degree of medical certainty." *See id.* at 752; *see also* Heller v. Shaw Indus., Inc., 167 F.3d 146, 153 n.4 (3d Cir. 1999) ("in a diversity case . . ., state rules on the degree of certainty required of an expert's opinion apply" and, "in Pennsylvania, a doctor can give an opinion on the cause of a plaintiff's illness [only] if he or she can do so with a reasonable degree of medical certainty") (citing Paoli).

Finally, and of particular significance here, are the standards of causation **[*18]** applicable in toxic tort cases. HN10 "To meet [his] causation burden, [the] plaintiff must first establish that" the substance in question "is capable of causing" in humans the injury alleged; this is known as "general causation." *See* Soldo, 244 F. Supp.2d at 524-25 (citations omitted). Then the plaintiff "must . . . establish that, in [his] particular case," the substance "did in fact cause" the injury he alleges, *i.e.,* "specific causation." *See id.; see also, e.g.,* Paoli, 35 F.3d at 752 (to sustain "traditional [toxic] tort

claims, . . . plaintiffs must show that they were exposed to the chemicals released by the defendants, that these chemicals can cause the types of harm they suffered, and that the chemicals in fact did cause them harm") (emphasis added); In re Breast Implant Litig., 11 F. Supp.2d 1217, 1224 (D. Colo. 1998) ("causation in toxic tort cases is discussed in terms of general and specific causation") (citation omitted).

It is with the foregoing standards in mind that the District Court should analyze the admissibility of the Plaintiff experts' testimony.

B. The Testimony and Opinions of Dr. [*19] Roberts Should Be Excluded Under the Aforementioned Standards.

Dr. Roberts' research and opinions most obviously go to the question of whether St. John's Wort generally is capable of causing cataracts in humans, so "general causation" is the logical starting point for the court's analysis. *Cf.* Soldo, 244 F. Supp.2d at 524-25. In this regard, all of Dr. Roberts' opinions flow directly from her animal studies, a topic addressed at length in Paoli.

The Paoli Court first discussed animal studies hypothetically, as a vehicle to explain Rule 702's "fit" requirement:

> HN11 Rule 702 requires that the expert's testimony must assist the trier of fact. . . . [Thus], admissibility depends in part on the proffered connection between the scientific research . . . and particular disputed factual issues in the case. . . .
>
> For example, HN12 animal studies may be methodologically acceptable to show that chemical X increases the risk of cancer in animals, but they may not be methodologically acceptable to show that chemical X increases the risk of cancer in humans. *Daubert* explains that, 'fit' is not always obvious, and scientific validity for one purpose **[*20]** is not necessarily scientific validity for other, unrelated purposes. . . . Thus, even if an expert's proposed testimony constitutes scientific knowledge, his or her testimony will be excluded if it is not scientific knowledge for purposes of the case. . . . Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.
>
> . . .
>
> [Thus], HN13 in order for animal studies to be admissible to prove causation in humans, there must be good grounds to extrapolate from animals to humans, just as the methodology of the studies must constitute good grounds to reach conclusions about the animals themselves. Thus, the requirement of reliability, or 'good grounds,' extends to each step in an expert's analysis all the way through the step that connects the work of the expert to the particular case.

See id., 35 F.3d at 742-43 (citations and most internal quotations omitted, emphasis added).

Consistent with Paoli, HN14 courts addressing animal studies commonly have identified the "extrapolation" inquiry as an important, if not threshold, determination for the purposes of both "fit" and "reliability. **[*21]** " *See id.* at 742-43, 779-81; *see also, e.g.,* General Elec. Co. v. Joiner, 522 U.S. 136, 144-46, 139 L. Ed. 2d 508, 118 S. Ct. 512 (1997) (affirming exclusion of evidence where there was no "explanation how and why the experts could have extrapolated their opinions from . . . seemingly far-removed animal studies" to humans; "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered") (citations omitted); Soldo, 244 F. Supp.2d at 546 ("to ensure that the expert's . . . animal studies [are] reliable, there must be a scientifically valid link -- such as supporting human data -- between the sources or studies consulted and the conclusion reached") (citations and internal quotations omitted); *see also id.* at 548 (same

inquiry related to "fit"); In re Diet Drugs, 2001 U.S. Dist. LEXIS 1174, 2001 WL 454586, *15 (E.D. Pa. Feb. 1, 2001) (evidence unreliable where plaintiff fails to explain reliance on "animal studies far removed from circumstances of [the] plaintiff's exposure") (citations omitted).

Paoli presents a good example of a case where sufficient grounds for extrapolation **[*22]** existed. Among other things, the Third Circuit Court emphasized that:

> . the animal studies in question were supported by human "occupational studies" and, "when there is a concordance of animal data and human data, it strengthens the reliability of each";
>
> . the "defendants' own experts based their opinions partly on animal studies[,] showing that they were at least relevant to assessing causation in humans";
>
> . "animal studies were particularly valuable with respect to assessing health effects of [the chemical in question], because humans and monkeys had shown similar sensitivity" to a related chemical compound; and
>
> . the "EPA had relied on animal studies to draw conclusions about the effects of [the chemical] on humans."

See id. 35 F.3d at 779-80.

None of these "good grounds" for extrapolation are present in the instant case. Thus far, there are no human studies to corroborate Dr. Roberts' *in vitro* animal testing and, thus, there exists no "concordance of animal data and human data" to "strengthen[] the reliability of each." *Compare* Paoli *with* discussion *supra* (noting lack of human studies). The Defendant has failed to validate Dr. **[*23]** Roberts' efforts by offering competing animal studies. *See id.* Dr. Roberts has not demonstrated a "similar sensitivity" between bovines and human beings to hypericin or St. John's Wort. *Cf.* Dep. Tr. of Dr. Roberts (providing no basis to conclude that metabolic processes of species would result in similar sensitivity to ingested hypericin). n5 Nor has the Plaintiff shown that the EPA, or any other governmental body, has relied on animal studies to draw conclusions regarding the effects of St. John's Wort on the human eye.

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n5 Dr. Roberts did testify that, although the eyes of "monkeys and primates" would be the best comparators, cow eyes biologically "are very close to humans." *See id.* at 87. While this similarity may justify the decision to soak bovine cells/lenses in hypericin in a test tube or petri dish, it does not show the type of "similar sensitivity" contemplated in Paoli. *See* discussion *supra* in text; *see also* discussion *infra* (concluding that *in vitro* data here presents too great an analytical gap to support Dr. Robert's theory of general causation).

- - - - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - - **[*24]**

As just seen, none of the earmarks of reliability and fit identified in Paoli are present in this case. To the contrary, the record on the whole reveals science that has taken the most preliminary (if arguably promising) steps towards establishing a causal connection between St. John's Wort and cataracts.

Although Dr. Roberts on occasion has appeared inclined to overstate the implications of her research, the tentative nature of her findings are apparent from the language of her publications. For example, while her Expert Report claims to opine "within a reasonable degree of scientific

certainty" that ingestion of St. John's Wort accelerates the formation of cataracts, her conclusions in the literature are stated with markedly less confidence. *See, e.g., Photooxidation* Article at 200 ("hypericin can induce changes in lens protein that could lead to the formation of cataracts"); *id.* at 203 (chemical properties of hypericin "should enable it to cross blood/ocular barriers"); *and id.* ("hypericin induces changes in lens proteins *in vitro* and this could lead to the formation of cataracts . . . *in vivo*") (emphases added); *see also, e.g., Fluorescence* **[*25]** Article at 597 *and* Dep. Tr. of Dr. Roberts at 43-45 (stating "it is essential to determine clinically whether hypericin reaches the human eye and whether it can be phototoxic to ocular tissues," discussing "development [of] a model system," but admitting that ocular fluorometry could not yet detect presence of hypericin in human eye); *cf. also Fluorescence* Article at 600 (positing that hypericin "binding might occur . . . in physiological conditions") (emphasis added).

Consistent with the foregoing, Defense counsel elicited the following concessions during Dr. Roberts' deposition, ones that are particularly damaging under Rule 702:

> Q. Just to clarify, Doctor, am I correct in stating that . . . what you know to this point in time is . . . St. John's Wort may or possibly can cause cataracts in humans?
>
> A. Yes.
>
> Q. You're not saying that [it] actually does; is that correct?
>
> A. You're right.
>
> Q. You need to do more studies to be able to confirm that . . .?
>
> A. That's correct.

See Dep. Tr. of Dr. Roberts at 141 (emphasis added).

By Dr. Roberts' own admission, her current research is insufficient to support **[*26]** a theory of general causation to any reasonable degree of certainty. *See* discussions *supra; see also generally* Paoli, 35 F.3d at 742 (HN15 Rule 702 does not permit expert testimony based on "subjective belief or unsupported speculation") (citation omitted). If and when further studies are available to effectively close the gaps identified above, such an opinion one day may be admissible. *Compare, e.g.,* discussion *supra* at n.5 (noting distinction between soaking of bovine ocular matter in hypericin solution and human beings' ingestion and metabolism of St. John's Wort such that hypericin may, or may not, end up in human eye) *with* Diet Drugs, 2001 U.S. Dist. LEXIS 1174, 2001 WL 454586 at *15 (rejecting expert opinion based on "animal studies far removed from circumstances of [the] plaintiff's exposure") (emphasis added). On the record presented here, however, that day has not yet come.

In light of the inadmissibility of Dr. Roberts' opinions regarding general causation, the court need not reach the issue of specific causation. *See* Soldo, 244 F. Supp.2d at 525 HN16 ("if [the] plaintiff has not demonstrated sufficiently reliable evidence of **[*27]** general causation, [his] claims fail and there is no need to consider specific causation") (citations omitted). Even were the court to do so, however, Dr. Roberts' "opinions" regarding Mr. Fabrizi specifically are inadequate.

First, Plaintiff's counsel has failed to demonstrate Dr. Roberts' qualification to testify regarding specific causation. The Third Circuit Court faced a similar scenario in Heller, where a "certified industrial hygienist" purported to opine on the causation of the plaintiffs' specific injuries:

> [The industrial hygienist has] opined . . . that the illness[es] suffered by the [plaintiffs] were caused by their prolonged exposure to the [chemicals] measured in their home and emitted by the . . . [defendant] . . . . We . . . are doubtful that a non-medical expert

such as [the hygienist] is qualified to testify as to the cause of someone's illness. . . .

While [the hygienist] was knowledgeable about studies on [the relevant chemicals] and illness, . . . he is not a physician and did not examine the [plaintiffs] nor discuss with them their symptoms or their medical histories. Thus, whatever his qualifications for testifying **[*28]** about the source and level of [chemicals] in the [plaintiffs'] house . . ., his qualification to offer an opinion on the ultimate cause of the [plaintiffs'] illnesses is another matter.

See id., 167 F.3d at 159 & n.9 (emphasis added).

The Heller Court's observations are entirely consistent with Pennsylvania law, n6 and they apply here with equal force. Dr. Roberts has never interviewed the Plaintiff, examined him, or seen his medical records. And although her Expert Report claims to state an opinion regarding specific causation, she repeatedly has disavowed the requisite knowledge and expertise to offer the same. *See, e.g.,* Dep. Tr. of Dr. Roberts at 11-12 (admitting lack of qualification to treat or diagnose patients); *id.* at 15 (not qualified to treat cataracts); *and id.* at 250 (declining Plaintiff counsel's invitation to review Mr. Fabrizi's medical records, stating "I would prefer not to evaluate medical records . . . [because] I'm not an M.D."); *see also, e.g.,* In re Diet Drugs, 2000 U.S. Dist. LEXIS 9661, 2000 WL 962545, *5 (E.D. Pa. Jun. 28, 2000) (Supreme Court "has made clear that HN17 a person, although qualified as an expert in **[*29]** one area of expertise, may be precluded from offering opinions beyond that area of expertise") (citation omitted). n7

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n6 *See, e.g.,* discussion *supra* HN18 (Pennsylvania law requires "unequivocal medical testimony" of causation, offered to "a reasonable degree of medical certainty") (citations omitted, emphasis added); Niklaus, 767 F. Supp. at 96 (in case involving eye injury, expert must be capable of "offering expert medical testimony" regarding "diagnosis" and "causation of . . . injuries to the eye") (emphasis added).

n7 To be clear, the District Court need not hold that Dr. Roberts' lack of qualification extends to the issue of general causation. *Cf. generally, e.g.,* Genty v. Resolution Trust Corp., 937 F.2d 899, 917 (3d Cir. 1991) ("medical doctors . . . are not the only experts qualified to render an opinion as to the harm [generally] caused by exposure to toxic chemicals").

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For all of these reasons, Dr. Roberts' opinions are inadmissible and they **[*30]** cannot sustain the Plaintiff's burden regarding causation.

C. The Testimony and Opinions of Dr. Lamperski Likewise Are Inadmissible.

As to general causation, Dr. Lamperski in large part piggy-backs on the opinions of Dr. Roberts. *See* Aff. of C. Lamperski at PP8-9 (claiming "particular[]" reliance on "clinical trial data and consultation with Dr. Joan Roberts"). n8 The only other source identified is "the anecdotal reports of premature cataract development in patients taking St. John's Wort." *See* Dr. Lamperski's Report at 3.

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n8 Although Dr. Lamperski more generally has claimed reliance on "learned publications and

treatises," neither he nor Plaintiff's counsel has identified any other research supporting their theory of general causation. *See id.; cf. also* Dep. Tr. of Dr. Roberts at 243 ("my work is the first indication that [hypericin is] phototoxic in the eye").

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Obviously, Dr. Lamperski cannot establish general causation through the inadmissible opinions and testimony of Dr. Roberts. **[*31]** *See* discussion *supra; cf. also generally* Robinson v. Ford Motor Co., 967 F. Supp. 482, 487 n.2 (M.D. Ala. 1997) (HN19 expert testimony that "simply parrots the opinion of another does not assist the trier of fact, and thus, is inadmissible under Rule 702"), *aff'd,* 144 F.3d 56 (11th Cir. 1998). As to anecdotal reports, neither the Plaintiff nor his expert has demonstrated that such "evidence" is an acceptable and/or sufficient basis for showing causation. The case law is uniformly to the contrary. *See, e.g.,* Soldo, 244 F. Supp.2d at 542 HN20 ("reliance on anecdotal case reports to support [an expert's] causation opinion[] is contrary to both good scientific practice and the *Daubert* case law") (citations omitted); Newton v. Roche Labs., Inc., 243 F. Supp.2d 672, 681 n.1 (W.D. Tex. 2002) (anecdotal reports "are universally regarded as an insufficient scientific basis for a conclusion regarding causation" because they "do not isolate and exclude potentially alternative causes, . . . do not investigate or explain the mechanism of causation," and "lack controls") (numerous citations omitted).

Dr. Lamperski has **[*32]** failed to offer admissible opinions or testimony regarding general causation, and this conclusion obviates the need to reach specific causation. *See* discussion *supra.* Even reaching the issue, however, the Plaintiff's expert evidence again comes up short.

Initially, the undersigned questions whether an internist like Dr. Lamperski is qualified to offer opinions regarding ocular injury. At least some Pennsylvania precedent would demand specific medical "expertise" in the "diagnosis . . . and . . . causation of injuries to the eye." *See, e.g.,* Niklaus, 767 F. Supp. at 96; In re Paoli, 2000 U.S. Dist. LEXIS 12993, 2000 WL 1279922 at *2 (citing Niklaus and holding same); *see also* Dep. Tr. of C. Lamperski at 11-12 (admitting he was not an ophthalmologist and that, if patient required treatment of eye disease, he would refer patient to said specialist). Even assuming a more liberal standard applies, Dr. Lamperski's lack of specific expertise in ophthalmology undermines the reliability of his testimony regarding specific causation. *See generally* Elcock v. Kmart Corp., 233 F.3d 734, 749 (3d Cir. 2000) HN21 ("an expert's level of expertise may affect **[*33]** the reliability of [his] opinion") (citations and internal quotations omitted).

Relatedly, Dr. Lamperski's opinions are in direct contradiction to those of treating ophthalmologist Dr. Salvitti, who has concluded that the Plaintiff's causation theory cannot be established to a reasonable degree of medical certainty. *See generally* discussion *supra.* This gives the District Court good grounds for rejecting Dr. Lamperski's opinions based on "lack[of] foundation and . . . unreliability." *See* Washington v. Armstrong World Indus., Inc., 839 F.2d 1121, 1123-24 (5th Cir. 1988) (holding same where physician "never actually examined [the plaintiff] but merely relied on examinations performed by [treating] physicians who reached different conclusions") (emphasis added). n9

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n9 Dr. Lamperski's opinions are further called into question by the circumstances through which they have come to be offered. It suffices to say that, HN22 when a physician who has never examined the plaintiff renders opinions solely for the purpose of advancing a lawsuit, said opinions will be met with at least some degree of skepticism under the law. *Cf. generally, e.g.,* Watkins v. Telsmith, Inc., 121 F.3d 984, 991 (5th Cir. 1997) (HN23 *Daubert* inquiry "evaluates whether the expert is a hired gun or a person whose opinion in the courtroom will withstand the same scrutiny that it would among his professional peers") (citation omitted, emphasis added); Braun v. Lorillard Inc., 84 F.3d 230, 235 (7th Cir.) (*Daubert* discourages "the hiring of reputable scientists . . . to

testify for a fee to propositions that they have not arrived at through the methods . . . they use when they are doing their regular professional work rather than being paid to give an opinion helpful to one side in a lawsuit") (emphasis added), *cert. denied,* 519 U.S. 992, 136 L. Ed. 2d 375 (1996); Soldo, 244 F. Supp.2d at 527-28 ("expert opinions generated as the result of litigation have less credibility than opinions generated as the result of academic research or other forms of 'pure' [science]"; "we may not ignore the fact that a scientist's normal work place is the lab or field, not the courtroom or the lawyer's office") (citations and internal quotations omitted).

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Finally, Dr. Lamperski's opinions regarding specific causation are lacking in substance under Rule 702. In essence, Dr. Lamperski purports to have conducted a "differential diagnosis" to exclude all potential causes of Mr. Fabrizi's cataracts other than St. John's Wort. *Compare* Paoli, 35 F.3d at 758 (differential diagnosis "is a [widely accepted] method that involves assessing causation with respect to a particular individual" through "an attempt to rule out alternative causes") *with, e.g.,* Dr. Lamperski's Report at 2 ("none of the other long-established potential causes of cataract formation appear to apply in Mr. Fabrizi's case"). Dr. Lamperski admitted in his deposition, however, that the only information he possessed regarding the Plaintiff was a handful of treatment records from other physicians. *See* Dep. Tr. of C. Lamperski at 20, 23. This is insufficient under the law.

As the Paoli Court explained:

> We agree . . . that *HN24*[the] performance of physical examinations, taking of medical histories, and employment of reliable laboratory tests all provide significant evidence of a reliable differential diagnosis, and that their absence **[*35]** makes it much less likely that a differential diagnosis is reliable. We reach this conclusion in part based on the [fact] . . . that these techniques are generally accepted as a standard part of differential diagnosis, and that such techniques significantly reduce the likelihood of erroneous results. . . . Moreover, performance of standard diagnostic techniques provides *prima facie* evidence that a doctor has considered [alternate] causes and has attempted to test his or her initial hypothesis as to cause.

See id., 35 F.3d at 758-59 (emphasis added).

Here, the proffered expert has engaged in none of the standard techniques of differential diagnosis. Dr. Lamperski candidly admits to never having seen or interviewed Mr. Fabrizi. Obviously, then, he has not conducted physical examination(s), taken the Plaintiff's medical history, or employed reliable laboratory tests in support of his opinions. *Cf. id.* Rather, Dr. Lamperski relies on the treatment records of other physicians, at least one of whom has expressly rejected the Plaintiff's theory of specific causation. *See* discussion *supra* regarding Dr. Salvitti. Under the circumstances, the **[*36]** proposed expert "has engaged in few [if any] standard diagnostic techniques," and he has offered "no good explanation as to why his . . . conclusion remain[s] reliable." *See* Paoli, 35 F.3d 760-61. n10

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n10 The Paoli Court contemplated that, based on the specific facts of a given case, "a doctor does not always have to employ all of [the specified] techniques in order for [his] differential diagnosis to be reliable." *See id.* 35 F.3d at 759 (emphasis added). The burden in this regard, however, remains with the expert, as he must "offer[a] . . . good explanation as to why his or her conclusion[s] remain[] reliable" in the absence of the standard techniques. *See id.* 35 F.3d at 760. Dr. Lamperski has offered no such explanation here. His reliance on other physicians' treatment records alone is particularly troubling, moreover, given the contrary opinions of primary treating ophthalmologist Dr.

Salvitti.

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Dr. Lamperski's opinions regarding causation, both **[*37]** general and specific, should be excluded under Rule 702 and *Daubert.*

D. Given the Plaintiff's Failure to Proffer Admissible Expert Testimony Regarding Causation, the Defendant Is Entitled to Summary Judgment.

HN25 Where a plaintiff fails to present admissible expert testimony regarding causation, courts routinely have granted summary judgment in favor of the defendant. *See, e.g.,* Heller, 167 F.3d at 165 (affirming entry of summary judgment based on "the total lack of causation evidence absent the [proffered but inadmissible] expert testimony"); Soldo, 244 F. Supp.2d at 576-77 (granting summary judgment because, "in the absence of expert testimony, [the] plaintiff has failed to demonstrate that [the Defendant's product] can and did cause her [injury]").

Technically, the Defendant's most recent Motion for Summary Judgment (Doc. 28) was denied without prejudice pending resolution of the *Daubert* Motions. *See generally* Order dated Feb. 4, 2003 (Doc. 61). In light of the recommendations above, however, requiring the Defendant to renew its request for summary judgment would be a matter of mere formality.

The Plaintiff has **[*38]** been afforded ample opportunity to present expert testimony and opinions regarding general and specific causation. All the evidence he has submitted fails under Rule 702 and *Daubert,* and any request to further pursue expert testimony would be unjustified. *See* discussion *supra* at n.4. Accordingly, summary judgment should be entered in favor of the Defendant on each of the Plaintiff's claims.

CONCLUSION

The Defendant's Motions to Exclude the Testimony of the Plaintiff's Expert Witnesses (Docs. 53 & 55) should be granted, and summary judgment should be entered in favor of the Defendant.

In accordance with the Magistrates Act, 28 U.S.C. § 636(b)(1)(B) and (C), and Rule 72.1.4 (B) of the Local Rules for Magistrates, objections to this report and recommendation are due by June 18, 2004. Responses to objections are due by June 28, 2004.

June 2, 2004

FRANCIS X. CAIAZZA

Chief U.S. Magistrate Judge

*1999 U.S. App. LEXIS 29273, **

FIRST BANK OF MARIETTA, Plaintiff-Appellant, v. **HARTFORD UNDERWRITERS** INSURANCE COMPANY, Defendant-Appellee.

No. 98-4284

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

1999 U.S. App. LEXIS 29273

November 3, 1999, Filed

NOTICE: [*1] NOT RECOMMENDED FOR FULL-TEXT PUBLICATION. SIXTH CIRCUIT RULE 28(g) LIMITS CITATION TO SPECIFIC SITUATIONS. PLEASE SEE RULE 28(g) BEFORE CITING IN A PROCEEDING IN A COURT IN THE SIXTH CIRCUIT. IF CITED, A COPY MUST BE SERVED ON OTHER PARTIES AND THE COURT. THIS NOTICE IS TO BE PROMINENTLY DISPLAYED IF THIS DECISION IS REPRODUCED.

SUBSEQUENT HISTORY: Reported in Table Case Format at: 1999 U.S. App. LEXIS 35425.

PRIOR HISTORY: ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO. 95-00466. Marbley. 9-29-98.

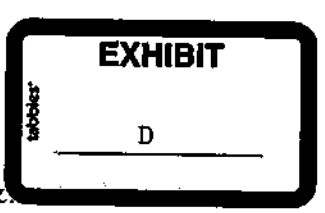
DISPOSITION: AFFIRMED.

CASE SUMMARY

PROCEDURAL POSTURE: Plaintiff bank appealed summary judgment for defendant insurer by the United States District Court, Southern District of Ohio, in an action to enforce fidelity bond insuring against dishonest losses from any "dishonest or fraudulent acts" by bank's employees, based on loss caused by an employee who increased customer's credit line without proper authorization.

OVERVIEW: Plaintiff bank appealed the district court's summary judgment for defendant insurer in an action to enforce fidelity bond insuring against dishonest losses from any "dishonest or fraudulent acts" by bank's employees, based on a loss caused by an employee who increased customer's credit line without proper authorization. The district court granted summary judgment because it found no genuine issue of material fact as to the employee's intent to financially benefit the customer in question. The court affirmed the result but held that the district court erred in its reasoning by considering plaintiff's inconsistent and untimely affidavits on another issue, filed in response to defendant's motion for summary judgment. The district court should not have considered such affidavits, and without them there was clearly no basis to find that plaintiff had raised any genuine issue of material fact at all in response to the motion.

OUTCOME: The court affirmed summary judgment for defendant insurer in bank's action to enforce insurance against dishonest losses from dishonest or fraudulent acts by bank employees. The district court ruled correctly but reasoned incorrectly. It should not have considered plaintiff's inconsistent and untimely affidavits on another issue.



CORE TERMS: summary judgment, genuine issue of material fact, interrogatory, insuring agreement, discovery, untimely, financial benefit, financially, line of credit, fictitious, dishonest, bonuses, fraudulent acts, fidelity bond, trade secrets, post-discovery, summary judgment motion, failed to produce, failed to present, intent to cause, receive credit, local business, genuine issue, credit line, authorization, conversation, negotiating, fraudulent, embezzled, indemnify

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Civil Procedure > Summary Judgment

Civil Procedure > Appeals > Standards of Review > De Novo Review

HN1 The court reviews de novo the district court's grant of summary judgment. More Like This Headnote

Civil Procedure > Summary Judgment > Burdens of Production & Proof

Civil Procedure > Summary Judgment > Summary Judgment Standard

HN2 Summary judgment is appropriate when there are no genuine issues of material fact in dispute and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). In deciding a motion for summary judgment, the court must view the evidence and draw all reasonable inferences in favor of the non-moving party. The judge is not to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial. A genuine issue for trial exists when there is sufficient evidence on which the jury could reasonably find for the plaintiff. More Like This Headnote

Civil Procedure > Summary Judgment > Supporting Papers & Affidavits

HN3 Fed. R. Civ. P. 56(e) allows affidavits to be considered to the extent that the facts contained therein are admissible into evidence. If an affidavit is untimely and inconsistent with a party's prior discovery responses, the affidavit is inadmissible and should not be considered. More Like This Headnote

Civil Procedure > Summary Judgment > Supporting Papers & Affidavits

HN4 Courts reject the tactic of attempting to defeat a summary judgment motion by filing an untimely affidavit that is inconsistent with prior discovery. It is accepted precedent that a party may not create a factual issue by filing an affidavit, after a motion for summary judgment has been made, which contradicts his earlier deposition testimony. More Like This Headnote

Civil Procedure > Summary Judgment > Supporting Papers & Affidavits

HN5 Matters inconsistent with admissions conclusively established under Fed. R. Civ. P. 36 cannot be considered by a court in ruling upon a motion for summary judgment. More Like This Headnote

Civil Procedure > Disclosure & Discovery

Civil Procedure > Discovery Methods > Expert Witness Discovery

HN6 It is proper for a court to exclude a party's expert testimony where the party possessed information to answer the expert interrogatory long before discovery closed, and yet failed to do so. More Like This Headnote

Civil Procedure > Disclosure & Discovery

Civil Procedure > Summary Judgment > Supporting Papers & Affidavits

HN7 A court must determine whether an untimely affidavit is inconsistent with a party's interrogatories, admissions, or depositions before deciding whether it creates a genuine issue of material fact. More Like This Headnote

COUNSEL: For FIRST BANK OF MARIETTA, Plaintiff - Appellant: James A. Giles, Giles & Williams, Mt. Vernon, OH.

For HARTFORD UNDERWRITERS INSURANCE COMPANY, Defendant - Appellee: William H. Woods, John J. Petro, McNamara & McNamara, Columbus, OH.

JUDGES: BEFORE: BATCHELDER, and GILMAN, Circuit Judges; and HOOD, District Judge. *

* The Honorable Denise Page Hood, United States District Judge for the Eastern District of Michigan, sitting by designation.

OPINIONBY: RONALD LEE GILMAN

OPINION: OPINION

RONALD LEE GILMAN, Circuit Judge. First Bank of Marietta and Hartford Underwriters Insurance Company entered into a fidelity bond insuring agreement pursuant to which Hartford agreed to indemnify First Bank for certain losses resulting **[*2]** from any "dishonest of fraudulent acts" committed by the bank's employees. One of First Bank's officers, Jerry Biehl, embezzled funds under the guise of two fictitious loans, and increased the credit line of a customer named Mascrete, Inc. without proper authorization. First Bank brought suit against Hartford to recover the losses sustained as a result of Biehl's conduct.

After First Bank filed suit, it accepted Hartford's previously outstanding offer to indemnify the bank for the embezzlement losses arising from Biehl's fictitious loans. Hartford, however, moved for summary judgment on the claim relating to Mascrete, arguing, among other things, that First Bank had failed to produce any evidence of Biehl's intent to cause the bank to sustain a loss or benefit Mascrete as required by the terms of the insuring agreement. The district court granted Hartford's motion. For the reasons set forth below, we **AFFIRM.**

I. BACKGROUND

A. First Bank's losses

Biehl, First Bank's Executive Vice-President and Chief Executive Officer, issued two fraudulent loans to fictitious individuals and then converted the proceeds to his personal use. Additionally, without proper authorization, Biehl **[*3]** increased the line of credit for Mascrete from $ 140,000 to $ 301,500 and then made advances against the credit line. Mascrete later went out of business and was unable to repay the loan.

After uncovering Biehl's conduct, First Bank filed a two-count complaint against Hartford, alleging a right to indemnification under the fidelity bond. Count 1 alleges that Biehl embezzled $ 87,974.44 by creating fictitious loans for his own benefit. Hartford did not contest Count 1 and has satisfied the loss. Consequently, the focus of this appeal is on Count 2.

B. Count 2

In Count 2, First Bank alleges that Biehl intentionally raised Mascrete's line of credit to $ 301,500 and personally approved advances to Mascrete in the amount of $ 261,981 in order to cause First Bank to suffer a loss and to financially benefit Mascrete. First Bank further alleges that at the time Biehl granted the increase in the line of credit and approved the advances, he knew that such actions were beyond the scope of his authority and could not be made without the prior approval of the bank's credit committee. Based on the above allegations, First Bank claims that the insuring agreement covers the loss associated **[*4]** with the Mascrete transactions.

C. Summary judgment, response, and reply

After the March 29, 1996 discovery deadline had passed, Hartford moved for summary judgment. Hartford set forth two primary arguments in support of its motion: (1) that First Bank had failed to produce any substantive evidence to support its claim that the Mascrete loss occurred as a direct

result of Biehl's "fraudulent or dishonest" conduct as defined in the fidelity bond, and (2) that First Bank had failed to perform a condition precedent to establishing Hartford's liability by refusing to furnish Hartford with the necessary paperwork documenting the bank's loss.

On July 31, 1996, First Bank filed a brief in response to Hartford's motion for summary judgment, attaching the affidavits of A Patrick Tonti, First Bank's Chairman of the Board, and Alan Shind, a First Bank vice president and director. The response utilizes the affidavits in an attempt to create a genuine issue of material fact as to Biehl's intent to cause the bank a loss and to financially benefit Mascrete. Specifically, Tonti states in his affidavit that Biehl told him in a private conversation on May 25, 1994 that Biehl engaged in **[*5]** the Mascrete transactions in order to "get even" with First Bank. Tonti goes on to note that in his opinion no reasonable officer would have raised Mascrete's credit limit to the level that Biehl had authorized.

In Hartford's reply, it asserted that the "surprise" affidavits of Tonti and Shind should not have been given any credence because they were filed two months after Hartford had moved for summary judgment, four months after discovery had ended, and eight months after First Bank had filed its answers to Hartford's interrogatories. Although Hartford objects to both affidavits, the real focus is on Tonti's affidavit because Shind's affidavit does not create a genuine issue of material fact.

Specifically, Hartford argues that Tonti's affidavit is inconsistent with First Bank's response to the following interrogatory:

> 5. With regard to any wrongful financial benefit obtained by Jerry L. Biehl and described in response to Interrogatory No. 4 above, describe: the nature of such benefit; the amount of such benefit; and the date or dates upon which Jerry L. Biehl received such benefit.
>
> Answer. Biehl was able to maintain his employment by demonstrating a certain amount **[*6]** of loan activity and performance. He hoped to receive credit towards possible bonuses. He further maintained his standing in the local business community. The dates Biehl received these benefits began with the first loan made to the borrowers listed on Exhibit 1 and continued through the duration of his employment with First Bank.

D. The district court's decision

The district court, relying on Tonti's affidavit, found that a genuine issue of material fact existed as to whether Biehl engaged in the Mascrete transactions in order to cause First Bank to sustain a loss. It also found, however, that First Bank had failed to present sufficient evidence to create a genuine issue of material fact as to whether Biehl intended to obtain a financial benefit for himself or another. In concluding that Mascrete did not receive an improper financial benefit as a result of Biehl's actions, the district court noted that First Bank's board of directors, including Tonti and Shind, had ratified the Mascrete transactions on May 25, 1994 by negotiating a new line of credit with Mascrete under essentially the same terms as Biehl's transactions and by advancing additional monies under the line **[*7]** of credit approved by Biehl. Because the district court found that there was no probative evidence that Biehl intended to financially benefit Mascrete, it expressly declined to address Hartford's alternative argument that First Bank's proof of loss was insufficient.

The district court entered a final and appealable judgment on September 29, 1998. On October 16, 1998, First Bank filed a timely notice of appeal. In its appeal, First Bank asserts, among other things, that the Tonti affidavit creates a genuine issue of material fact as to whether Biehl intended to financially benefit Mascrete. First Bank also argues that it did not ratify Biehl's conduct by negotiating and doing business with Mascrete after it had discovered Biehl's unauthorized transactions, but rather was mitigating its losses.

II. ANALYSIS

A. Right decision - wrong reason

The district court's judgment will be affirmed, but not for the reasons set forth in its opinion. In granting Hartford's summary judgment motion, we are of the opinion that the district court erred when it considered First Bank's inconsistent and untimely affidavits filed in response to Hartford's motion for summary judgment. Without **[*8]** such affidavits, there is clearly no basis to find that First Bank has raised a genuine issue of material fact in response to Hartford's motion.

B. Standard of review

HN1 We review *de novo* the district court's grant of summary judgment. *See,e.g.,* HN2 *Smith v. Ameritech*, 129 F.3d 857, 863 (6th Cir. 1997). Summary judgment is appropriate when there are no genuine issues of material fact in dispute and the moving party is entitled to judgment as a matter of law. *See* FED. R. CIV. P. 56(c). In deciding a motion for summary judgment, the court must view the evidence and draw all reasonable inferences in favor of the non-moving party. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986). The judge is not "to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986). A genuine issue for trial exists when there is sufficient "evidence on which the jury could reasonably find for the plaintiff." *Id.* at 252. **[*9]**

C. The district court did not err in granting Hartford's motion for summary judgment

1. Insuring agreement

This case essentially hinges on how the following clause in the insuring agreement applies to the loss sustained as a result of Biehl's transactions with Mascrete:

> The Underwriter, in consideration of an agreed premium, and in reliance upon all statements made and information furnished to the Underwriter by the Insured in applying for this bond, and subject to the Declarations, Insuring Agreement, General Agreements, Conditions and Limitations and other terms hereof, agrees to indemnify the Insured for:
>
> (A) Loss resulting directly from dishonest or fraudulent acts committed by an Employee acting alone or in collusion with others.
>
> Such dishonest or fraudulent acts must be committed by the Employee with the manifest intent:
>
> (a) to cause the Insured to sustain such loss, and
> (b) to obtain financial benefit for the Employee or another person or entity.
>
> . . .
>
> As used throughout this Insuring Agreement, financial benefit does not include any employee benefits earned in the normal course of employment, including: salaries, commissions, **[*10]** fees, bonuses, promotions, awards, profit sharing or pensions.

2. Relevant Sixth Circuit case law

After considering Tonti's affidavit, the district court found that there was a genuine issue of material fact as to whether Biehl intended to cause First Bank a loss, but nonetheless granted summary judgment on the basis that First Bank had failed to present any evidence of Biehl's intent to financially benefit Mascrete. In support of its ruling, the district court relied on *Municipal Securities, Inc. v. Insurance Co. of North America*, 829 F.2d 7 (6th Cir. 1987), and *FDIC v. St. Paul Fire and Marine Ins. Co.*, 942 F.2d 1032 (6th Cir. 1991). We find no need to discuss the applicability of these cases, however, nor to pass on the merits of First Bank's arguments regarding the district court's analysis, because without the Tonti affidavit there is simply no basis to find that Biehl intended to cause the bank a loss.

3. Error in considering the Tonti affidavit

HN3 Rule 56(e) of the Federal Rules of Civil Procedure allows affidavits to be considered to the extent that the facts contained therein are admissible into evidence. If an affidavit is untimely **[*11]** and inconsistent with a party's prior discovery responses, the affidavit is inadmissible and should not be considered for the reasons set forth below.

In *Gagne v. Northwestern Nat. Ins. Co.*, 881 F.2d 309 (6th Cir. 1989) (overruled on other grounds), HN4 this court rejected the tactic of attempting to defeat a summary judgment motion by filing an untimely affidavit that is inconsistent with prior discovery: "It is accepted precedent that a party may not create a factual issue by filing an affidavit, after a motion for summary judgment has been made, which contradicts his earlier deposition testimony." *Id.* at 315 (internal citations and quotations omitted). Furthermore, in *Reid v. Sears, Roebuck & Co.*, 790 F.2d 453, 460 (6th Cir. 1986), the court noted that summary judgment would be greatly diminished as a mechanism for screening out frivolous issues of fact if a party could create a factual dispute simply by presenting an affidavit contradicting his prior testimony.

The case of *Hickory Specialties, Inc. v. Forest Flavors Int'l, Inc.*, 12 F. Supp. 2d 760 (M.D. Tenn. 1998), is also persuasive and insightful. In *Hickory* **[*12]** *Specialities*, the plaintiff attempted to introduce a belated list of an additional thirty-six recently identified trade secrets through the untimely affidavit of its expert witness when it had previously submitted a list of only thirty-one trade secrets in its response to the defendant's interrogatories. Even though the expert's affidavit was filed only three days after the close of discovery, the court held that the plaintiff was precluded from introducing inconsistent post-discovery proof in the form of the expert's affidavit. *Id.* at 770-71. In support of its reasoning, the *Hickory Specialities* court stated as follows:

> First, according to *Haun v. Humana, Inc.*, 651 F. Supp. 120, 122 (W.D. Ky. 1986), "Matters HN5 inconsistent with admissions conclusively established under Rule 36 cannot be considered by the Court in ruling upon Defendant's Motion for Summary Judgment." According to *Haun*, the Court should not allow HSI to file a post-discovery affidavit that is inconsistent with HSI's 14 month old interrogatory answer. Second, *Minnkota Power Cooperative, Inc. v. Manitowoc Co., Inc.*, 669 F.2d 525, 528-29 (8th Cir. 1982), **[*13]** explains how HN6 it is proper for a court to exclude a party's expert testimony where the party possessed information to answer the expert interrogatory long before discovery closed, and yet failed to do so.
>
> 12 F. Supp. 2d at 770.

Thus, based on the principles laid out in *Gagne, Reid*, and *Hickory Specialities*, HN7 a court must determine whether an untimely affidavit is inconsistent with a party's interrogatories, admissions, or depositions before deciding whether it creates a genuine issue of material fact. In the case at bar, the Tonti affidavit is inconsistent with First Bank's responses to Interrogatory No. 5.

Tonti's affidavit references a private conversation that he and Biehl allegedly had immediately following the board of directors' ratification of the Mascrete transactions on May 25, 1994. Tonti's

allegation that Biehl told him that he engaged in the Mascrete transactions in order to get even with the bank is inconsistent with First Bank's interrogatory answer that Biehl engaged in the Mascrete transactions in order to increase his standing in the local business community, maintain his employment, and receive credit toward possible bonuses. Obviously, if Biehl deliberately **[*14]** made the loan in order to sabotage the bank, his reputation in the business community would be damaged, he would be less likely to maintain his employment, and he would not receive any bonuses. Because Tonti's untimely affidavit was inconsistent with First Bank's earlier interrogatory response, the district court should not have given the affidavit any consideration. Without the Tonti affidavit, there is no genuine issue of material fact remaining in dispute.

III. CONCLUSION

For all of the reasons set forth above, we **AFFIRM** the decision of the district court.